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| 09/581,515 | 07/27/2000 | MICHEL PUECH | 065691/0194 | 6785 |

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WASHINGTON, DC 20007

EXAMINER

IMAM, ALI M

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| ART UNIT | PAPER NUMBER |
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3737

DATE MAILED: 07/16/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,515

Applicant(s)

PUECH, MICHEL

Examiner

Ali Imam

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/30/3 (RCE).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 33 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 33 and 35 recite the limitation "the human" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel (US 4,276,491).

In regard to claims 33 and 35, Daniel teaches a device for deep penetration echographic exploration of tissues or organs of a human or animal body (col. 1, line 26 and col. 2, lines 65-66) comprising a transceiver system (10) operating in the high frequencies (col. 1, line 14); and an ultrasound transducer (in the transceiver system) inherently having a focal length capable of deep penetration which includes the macular region or the posterior wall of the eye.

Art Unit: 3737

In regard claims 32 and 34, the reference meets all the claimed structures as stated above. The method claimed by the applicant concerning the steps of making a device and providing an ultrasound transducer is inherently met by the disclosure.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 2, 5, 10, 12, 13, 17-19, 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. (US 5,776,068) in view of Chapelon et al. (US 5,666,954).

In regard to claims 1, 2, 5, 10, 12, 13, 17-19, and 28-35, Silverman teaches in col. 3, lines 57-60, a method and device for ultrasound deep penetration and tissue characterization of human eye by the step and structure for providing an ultrasound transducer having a nominal excitation frequency of 50 Mhz and a focal length of about 10 mm.

Silverman fails to mention specifically that the focal length can be also in the range of 20mm to 25 mm.

Chapelon teaches in col. 5, line 16, an ultrasound transducer capable of having focal length in the range of 20 mm to 70 mm. Chapelon further teaches that an operator selects a specific focal length depending on the desired penetration depth for the soundwaves.

Chapelon is evidence that one of ordinary skill in the art in the field of ultrasound eye scanning would recognize the benefit of using a transducer having focal length in the range of 20

Art Unit: 3737

mm to 70 mm since deep penetration is required for imaging the posterior wall (e.g., the macula) of the eye.

Therefore, it would have been obvious to an ordinary skill in the art at the time the invention was made to modify Silverman's transducer such that it is capable of providing focal length of 20 mm to 25 mm in order to penetrate deep into the eye as suggested by Chapelon.

In regard to claims 27 and 29-31, Silverman further teaches in Fig. 2, an electronic scanning system which includes the items for exciting and amplifying the receive echo signals.

6. Claims 14-16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. (US 5,776,068) in view of Chapelon et al. (US 5,666,954) as applied to claims 1, 2, 5, 10, 12, 13, 17-19, 27-35 above, and further in view of Zeimer (US 4,883,061).

The combined invention of Silverman and Chapelon teaches all the limitations of the claimed subject matter except for mentioning specifically that the method and device for ultrasound imaging of the eye includes the imaging of posterior segment of the eye. Zeimer teaches in the abstract an ultrasound method and apparatus for penetrating the retinal or nerve fiber layer wherein one of the step or structure involves receiving ultrasound beam from the interior as well as posterior surfaces of the retina (e.g., macula, see col. 1, line 27). Silverman, Chapelon, and Zeimer are combinable because they are from the same field of endeavor, that is the ultrasound tissue analysis of human body. At the time of the invention, it would have been obvious to an ordinary skill in the art to use Zeimer's method of penetrating posterior surface of the eye in using the combined invention of Silverman and Chapelon's ultrasound method and

Art Unit: 3737

device. The motivation for doing so would have been to diagnose and detect eye diseases, for example, papilledema at an early stage (see col. 1, lines 21-33 of Zeimer).

7. Claims 1, 2, 5, 10, 12, 13, 17-19, 27-35 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. ("Three-dimensional High frequency Ultrasonic Parameter Imaging of Anterior Segment Pathology", Ophthalmology 1995 of record) in view of Chapelon et al. (US 5,666,954).

Silverman teaches all the limitation of the claimed subject matter except for mentioning specifically the focal length of 20 mm to 25 mm and the step or structure for moving the ultrasound transducer.

Chapelon teaches in col. 5, line 16, an ultrasound transducer capable of having focal length in the range of 20 mm to 70 mm. Chapelon further teaches that an operator selects a specific focal length depending on the desired penetration depth for the soundwaves.

Chapelon is evidence that one of ordinary skill in the art in the field of ultrasound eye scanning would recognize the benefit of using a transducer having focal length in the range of 20 mm to 70 mm since deep penetration is required for imaging the posterior wall (e.g., the macula) of the eye.

Therefore, it would have been obvious to an ordinary skill in the art at the time the invention was made to modify Silverman's transducer such that it is capable of providing focal length of 20 mm to 25 mm in order to penetrate deep into the eye as suggested by Chapelon.

8. Claims 3, 4, 6-9, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silverman et al. ("Three-dimensional High frequency Ultrasonic Parameter Imaging of Anterior

Art Unit: 3737

Segment Pathology”, Ophthalmology 1995 of record) in view of Chapelon et al. (US 5,666,954) as applied to claims 1, 2, 5, 10, 12, 13, 17-19, 27-35 above, and further in view of Coleman et al. (US 5,331,962) or Reinstein et al. (US 5,293,871).

The combined invention of Silverman and Chapelon teach all the limitations of the claimed subject matter except for mentioning specifically that the method and device for ultrasound imaging of the eye includes the imaging of posterior segment of the eye.

Coleman teaches in Fig. 3, a motor (38 or 26) coupled with an ultrasound imaging system for imaging anterior structures of a human eye. Reinstein teaches in col. 3, line 64 – col. 5, line 43, an ultrasound transducer attached to a motor (28). Silverman, Chapelon, Reinstein, and Coleman are combinable because they are from the same field of endeavor, that is the ultrasound tissue analysis of human body. At the time of the invention, it would have been obvious to an ordinary skill in the art to use Coleman’s method of moving the ultrasound transducer by adding a motor, as suggested by Reinstein to the combined invention of Silverman and Chapelon’s ultrasound imaging device. The motivation for doing so would have been to properly align the transducer for accurate diagnosis of the diseased area of the eye.

Drawings

9. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the transducer with a membrane of plastics material, motor, and transceiver must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Art Unit: 3737

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Conclusion

10. Copies of previously provided references would not be provide in this office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Imam whose telephone number is 703-305-0028. The examiner can normally be reached on Mon. - Th., 8:00- 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703-308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Ali Imam
Examiner
Art Unit 3737

AMI
July 12, 2003